

**REMARKS**

This Amendment is being filed in response to the Office Action mailed November 15, 2005. Applicant previously elected Claims 1-8, withdrew Claims 9-26, and added Claims 27-35. Accordingly, Claims 1-8 and 27-35 are pending.

**CLAIM REJECTIONS – CLAIMS 1, 2, 7, 27-30, 32 & 33-35 – 35 USC § 102(b)**

Claims 1, 2, 7, 27-30, 32 and 33-35 were rejected under 35 USC § 102(b) as being anticipated by Munsch (US 5,840,151).

Applicant's claimed invention is directed to a package for an elongate surgical device. The package comprises an elongate tube that is formed into a coiled configuration having coiled portions. A weld bonds the coiled portions together such that the portions cannot be peeled from each other. In particular, Claims 1 and Applicant has herein amended independent Claims 1, 27 and 33 to further clarify that the coiled portions are bonded by the weld in a non-peelable relationship. In fact, the weld is of sufficient strength that detaching the coiled portions from each other would break the package and render it useless. By "peelable", Applicant is referring to the normal application of manual force by a user's hands. Of course, nearly any bond can be separated with excessive force. Thus, "non-peelable" refers to a bond that cannot be separated without excessive force. In other words, a "non-peelable" bond as recited in Applicant's claims could not be easily separated through application of normal, manual force. Applicant has amended independent Claims 1, 27 and 33 to recite such a feature.

Munsch not only fails to disclose a non-peelable coil, it actually teaches the very opposite. The Background of the Invention discusses the problems associated with tubular assemblies in parenteral or intravascular or intravenous (I.V.) solution delivery systems, such as the “great deal of time and effort separating the tubes from each other for use.” Thus, one of Munsch’s primary objectives is to make it easier for a user of these I.V. tubular assemblies to separate the coils:

- At the very outset of the Detailed Description, Munsch states Figure 1 shows “an apparatus 10 for forming **peelable** tube assemblies 12 of tubular members . . . ” (col. 6:63-64, *emphasis added*).
- Not only is the tube assembly in Munsch peelable, “it is preferred that the coiled peelable tube assembly 12 such as formed with the apparatus 10 be **easily separated** into individual tubular members 12a and 12b by the parties, particularly those in a weakened state.” (col. 7:55-59; *emphasis added*).
- Munsch aims to make it easy for patients, particularly those in a weakened state, to peel the tubes: “ . . . the patient can grab the fitting 44 in one hand and the free ends 46 of the tubes 12 in their other hand and by exerting a pull force, such as on the fitting 44 or on the free ends 46 or on both, break all the webs 22 between the adjacent coils of the tubes 12a and 12b in a single separating step and thereby peel the tubes 12a and 12b from one another in a relatively quick and easy fashion.” (col. 8:5-11).

The Office Action cites MPEP § 2111.02 which states that the intended use may further limit the claim if it does more than merely state purpose or intended use. Here,

Applicant's intended use is directly tied to the structure of the package. Since Applicant's intended use is directed to storing an elongate surgical device and not to delivering fluid, Applicant's package remains in a fixed, non-peelable coiled configuration as claimed. Munsch's tubular assembly, on the other hand, is intended to deliver fluid. Accordingly, Munsch's assembly, though initially coiled, must be peeled part and straightened for use in delivering fluid.

Applicant has also amended independent Claims 1 and 27 to recite that the package would be rendered useless if the first coiled portion is detached from the second coiled portion. As discussed above, the non-peelable bond between the coiled portions cannot be separated using normal manual force. To the extent that excessive force is applied to separate the coiled portions from each other, Applicant's package would be rendered useless. To the contrary, separating the coils in Munsch's tubular is necessary for use. Munsch's assembly is intended for operation after the quick and easy peeling of the coils.

#### **CLAIM REJECTIONS – CLAIMS 3-8 & 31 – 35 USC § 103(a)**

Claims 3, 7, 8 and 31 were rejected under 35 USC § 103(a) as being unpatentable over Munsch in view of Yasha-Heifetz (US 3,312,579). The Office Action states it would have been obvious to one of ordinary skill in the art to modify Munsch by forming a continuous weld as suggested by Yasha-Heifetz in order to form a more securely united structure.

To establish a prima facie case of obviousness, three basic criteria must be met:

1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

2) there must be a reasonable expectation of success; and

3) the prior art reference(s) must teach or suggest all the claim limitations.

*MPEP* § 2142.

With reference to the Office Action, the mere fact that references may be combined or modified is insufficient to establish obviousness. See *MPEP* §2143.01. There must be motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the references. In other words, the primary question is:

- Is there motivation in Munsch to suggest a combination with Yasha-Heifetz, or vice-versa?

The answer is clearly no. As discussed above, Munsch actually teaches away from a non-peelable relationship between coiled portions. Munsch strives to make its tubular assembly, though initially coiled, as easily peelable as possible, especially for weakened users. The “quick and easy” separability in Munsch (col. 8:11) is in accordance with the tubular assembly’s intended use of delivering fluids.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Here, combining Munsch with Yasha-Heifetz would completely defeat the purpose of Munsch. In particular, Munsch’s tubular assembly cannot be peeled in a

“relatively quick and easy fashion” if the reference is combined with Yasha-Heifetz which teaches welding of tubes together. Accordingly, Applicant respectfully submits that there is no motivation or suggestion to combine Munsch with Yasha-Heifetz.

Claim 8 was rejected under § 102(b) or § 103(a) in the alternative over Munsch. Claim 8 ultimately depends on Claim 1 which, as discussed above, is not anticipated or made obvious by Munsch.

Claims 4-6 were rejected under 35 USC 103(a) as being unpatentable over Munsch in view of Jaeschke et al (US 4,332,322). Claims 4-6 ultimately depend on Claim 1. The addition of Jaeschke to Munsch nonetheless fails to disclose or suggest all the limitations recited in Claim 1, namely, a weld bonding the coiled portions in a non-peelable relationship, the weld being so strong that the package is rendered useless should the coiled portions be detached from one another.

Accordingly, Applicant respectfully submits that independent Claims 1, 27 and 33 are allowable over the cited prior art references. Applicant further submits that the dependent claims are allowable for the additional features recited therein.

Applicant encourages the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

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Patent Application

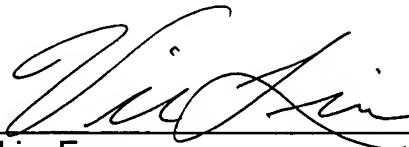
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Signature

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